ATTACHMENT B

REMARKS

By this amendment, Applicants have amended the claims so that the present invention is directed to monoclonal antibodies to Map10 which are clearly not disclosed or suggested in the prior art. In addition, other minor changes or deletions have been made to the claims where necessary to be consistent with the language of amended Claim 1, and the language of Claim 8 has been amended to address other objections. New Claim 30 has been added which is directed to monoclonal antibodies having the same epitope recognition of the specific H07 monoclonal antibody referred to in the specification, and Claims 31 and 32 are added which are of the same type as allowed Claims 25 and 26, except that they are directed to the nucleic acids encoding the variable light and heavy sequences. In light of the fact that the monoclonal antibodies as claimed in the present application are clearly not disclosed or suggested in the prior art, the present application is in condition for immediate allowance.

In the Official Action, the Examiner made an objection to Claim 8 which reflected some confusion in that the Examiner seemed to indicate that the antibody did not need to bind to Map10. In addition, the Examiner objected to Claim 8 in that he was unclear what the term "same specificity" referred to. Applicants have overcome these objections in that Claim 8 has been amended to now refer to the fact that some of the monoclonal antibodies of Claim 1 will recognize the same epitopes recognized by the full MAP protein, and one skilled in the art would recognize the scope of this claim and that it constitutes a subset of the monoclonal antibodies of Claim 1, which will not necessarily recognize the same epitopes as monoclonal antibodies recognizing the

MAP protein. Accordingly, the Examiner's objections to Claim 8 are respectfully traversed in the present amendments.

In the Final Rejection, the Examiner maintained the rejection Claims 1-4, 13 and 24 under 35 U.S.C. §102(b) as anticipated by the Hook et al. patent, US 5,648,240. In particular, the Examiner argued that the "capable of" language was "intended use" language which was not "given patentable weight". Such an argument is in complete contradiction with the United States Patent and Trademark Office's own Written Description Guidelines which were discussed in Applicants' previous response wherein it was pointed out that the USPTO considers the language "An isolated antibody capable of binding to antigen X" suitable under the Written Description Requirement. Under the Examiner's view, this claim would be interpreted as "An isolated antibody" which could mean any antibody in the world. It is completely untenable to take the position that the USPTO is telling Applicants that it is suitable to use the language "An isolated antibody capable of binding to antigen X", but then allow its Examiners to interpret such a claim as "An isolated antibody" by ignoring the target antigen to which it binds. Accordingly, the Examiner's position is in complete contradiction with the Patent Office's own guidelines and cannot be correct.

In any event, Applicants have amended Claim 1 to be directed to a monoclonal antibody that binds to the Map10 protein of *Staphylococcus aureus*, and this language is clearly directed to the specific and patentable subject matter of the claim. The Map10 monoclonal antibody of the present claims is clearly not disclosed or suggested in the Hook et al '240 patent. In particular, the Hook '240 patent discloses the full MAP protein without any disclosure or suggestion of any binding region, much less the specific

Map10 binding region as set forth in the present claims, and moreover only discloses polyclonal antibodies and **not** monoclonal antibodies. Because the Hook '240 patent does not disclose or suggest the specific Map10 region, nor discloses or suggest any monoclonal antibodies, it certainly does not provide any motivation or suggestion of generating monoclonal antibodies directed towards the specific Map10 region as set forth in the claims of the present application. This is particularly true in light of the fact that it is hard to predict which monoclonal antibodies will be effective. See attached Abstract from Ichiman et al., Can J. Microbiol. 37:404-407 (1991) showing that certain monoclonals afforded protection whereas others did not. Accordingly, in light of the fact that there is no disclosure, motivation or suggestion in the Hook '240 patent of any monoclonal antibody that can bind to any particular region, much less the specific Map10 region that the present monoclonal binds to, the present claims are patentable over the Hook '240 patent, and the Examiner's objections on the basis of this reference are respectfully traversed and should be withdrawn.

In the Official Action, the Examiner also rejected Claims 13-14 and 24 under 35 U.S.C. §102(b) on the basis of the Hook '240 patent and rejected Claims 5-8 under 35 U.S.C. 103(a) on the basis of Hook '240 and the Hook 6,288,214 patent. However, since all of these claims ultimately depend on Claim 1 (or have been canceled without prejudice), they are patentable for at least the reasons set forth above with regard to Claim 1, namely that monoclonal antibodies are not disclosed or suggested in Hook '240, nor is there any motivation or suggestion to make a monoclonal antibody to **any** particular subregion of the MAP protein, much less the **specific Map10 protein** which is the subject of the monoclonals of the present claims. Moreover, there is no teaching or

even a remote suggestion in the Hook '214 patent of monoclonals to the Map10 protein, particularly since the '214 patent is not even directed to the MAP protein at all, much less the specific Map10 region that is the target of the monoclonal antibodies of the present claims. Accordingly, the Examiner's other rejections on the basis of the Hook '240 patent are respectfully traversed and should be withdrawn.

In light of the amendments and arguments as set forth above, Applicants submit that the present application overcomes all prior rejections and has been placed in condition for allowance. Such action is earnestly solicited.

END OF REMARKS

1: Can J Microbiol. 1991 May;37(5):404-7.

Monoclonal IgM antibody protection in mice against infection with an encapsulated strain of Staphylococcus epidermidis.

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Passive protective activities of three different classes of monoclonal antibodies in mice against challenge with strain ATCC 31432 (capsular type I) of Staphylococcus epidermidis were examined. Monoclonal IgM antibody passively protected mice against challenge with the homologous strain, whereas monoclonal IgG1 and IgG2b antibodies did not. The protective activity of IgM was absorbed by the cell surface antigen extracted from the homologous strain but not by the antigen from heterologous strains. Rapid reduction of viable cells took place in the peritoneal cavity of mice immunized with monoclonal IgM as early as 6 h after the challenge with the homologous strain. An enzyme-linked immunosorbent inhibition assay showed there was remarkable inhibition with the homologous cell surface antigen but not with heterologous preparations from other strains. Results suggest that in the mouse the major passive protection against the S. epidermidis strain is provided by the IgM antibody to the cell surface antigen.

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APPENDIX 1